

Mail Stop Interference  
P.O. Box 1450  
Alexandria VA 22313-1450  
Tel: 571-272-4683  
Fax: 571-273-0042

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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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PAUL J. **CARTER** AND LEONARD G. PRESTA  
Junior Party  
(Patent 6,639,055),

v.

JOHN ROBERT **ADAIR**, DILJEET SINGH ATHWAL,  
AND JOHN SPENCER EMTAGE  
Senior Party  
(Application No. 11/284,260),

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Patent Interference No. 105,762  
(Technology Center 1600)

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*Before* RICHARD TORCZON, SALLY GARDNER LANE, and SALLY C.  
MEDLEY, *Administrative Patent Judges*

LANE, *Administrative Patent Judge*

**Order- Decision on Motions**

## I. STATEMENT OF THE CASE

The interference is before a panel for consideration of a Carter threshold motion seeking judgment that the single involved Adair claim is barred under 35 USC 135(b)(1).

### The Interference

#### *Parties*

Junior party Carter is involved on the basis of its patent 6,639,055 ("the Carter '055 patent"), which issued 28 October 2003, from application no. 09/705,686, filed 2 November 2000. (Paper 1 at 3). Claims 1-3, the only claims of the Carter '055 patent, were designated as corresponding to the Count. (Paper 1 at 4.)

Carter was accorded priority benefit as to the Count of application no. 08/146,206, filed 17 November 1993, now patent 6,407,213, which issued 18 June 2002, and application no. 07/715,272, filed 14 June 1991, now abandoned. (Paper 1 at 5).

The real party-in-interest of Carter is Genentech, Inc. (Paper 9).

Senior party Adair is involved on the basis of its application no. 11/284,260 ("Adair '260 application"), filed 21 November 2005. (Paper 1 at 3). Claim 26, Adair's only pending claim, was designated as corresponding to the Count. (Paper 1 at 4).

Adair was accorded priority benefit as to the Count of application no. 08/846,658, filed 01 May 1997; application no. 08/303,569, filed 07 September 1994, which issued as 5,859,205 on 12 January 1999; application no.

07/743,329, filed on 17 September 1991 (“the Adair ‘329 application”); application PCT/GB90/02017, filed 21 December 1990 (“the Adair PCT application”); and application GB 8928874.0, filed 21 December 1989. (Paper 1 at 5).

The real party-in-interest of Adair is UCB Pharma, S.A. (Paper 4).

#### *Subject Matter*

The parties’ claims are drawn to an antibody that has been “humanized,” that is, has a combination of human and non-human regions and specific amino acids. Humanization allows antibodies to be raised, in the laboratory, in non-human animals (for example, in mice) against antigens of interest and then changed so that they appear to the patient’s body as if they were human antibodies. Humanized antibodies are beneficial because they do not raise dangerous anti-immunoglobulin responses in human patients, as non-human antibodies can. (Carter ‘055 patent col. 1, l. 53, through col. 2, l. 35). The humanized antibodies of the involved Carter and Adair claims and the Count are antibodies that have a non-human Complementarity Determining Region (“CDR”), that is the region that binds antigen, and specifically recited non-human substitutions in other regions, called the Framework Regions (“FR”), of the antibody.

## **II. MOTION**

Carter’s Substantive Motion 1 (“Motion”) requests judgment barring involved Adair claim 26 under 35 U.S.C. § 135(b)(1). (Paper 23). Adair filed an Opposition (“Opposition”; Paper 80), and Carter replied (“Reply”; Paper 87). As

the moving party, Carter has the burden to show that it is entitled to the relief requested in its motion. Bd. R. 208(b).

Findings of Fact

1. The involved Carter '055 patent issued 28 October 2003. (Ex. 2001; Carter '055 Patent).
2. The "critical date" by which Adair must have filed claims to the same or substantially the same subject matter as claimed in the '055 patent, under 35 U.S.C. § 135(b)(1), is 28 October 2004.
3. Adair has a single involved claim, claim 26, which reads as follows:  
  
A humanized antibody light chain variable domain comprising non-human complementarity determining region amino acid residues which bind an antigen and a human framework region wherein said framework region comprises a non-human amino acid substitution at residue 46, as numbered according to Kabat.  
  
(Paper 5).
4. The involved Adair '260 application was filed 21 November 2005. (Ex. 2002; Transmittal for Adair '260 application).
5. The involved Adair '260 application was filed more than one year after the involved Carter '055 patent issued and after the critical date.
6. Prior to filing the involved '260 application, Adair filed application no. 10/938,117 ("the '117 application"), claiming priority to application no. 07/743,329, to which Adair's involved '260 application also claims priority.<sup>1</sup> (Ex. 2051, p. 2).

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<sup>1</sup> Carter incorrectly states that Adair's involved '260 application is a continuation of the '117 application. (Motion 5).

7. In a Preliminary Amendment to the '117 application, filed 28 October 2004, Adair filed new claims 30-32. (Ex. 2004, Amendment to the '117 application, filed 28 October 2004, p. 3-4).

8. Adair asserted that new claims 30-32 in the '117 application were copied from the involved Carter '055 application, in compliance with 35 U.S.C. § 135(b). (Ex. 2004, Preliminary Amendment to the '117 application, filed 28 October 2004, p. 5).

9. Adair relied on copied claims 30-32 of the '117 application for compliance with 35 USC 135(b)(1) when it requested an interference in the involved '260 application. (Ex. 2006, Preliminary Amendment and Request for Interference in application no. 11/284,260, filed 21 November 2005, p. 4).

10. Adair filed claims identical to the Carter '055 patent claims before the critical date.

11. Claim 30 of the '117 application recited:

A humanized antibody variable domain comprising non-human CDR amino acid residues which bind an antigen incorporated into a human antibody variable domain, and further comprising a Framework Region (FR) amino acid substitution at a site selected from the group consisting of:

4L, 35L, 38L, 43L, 44L, 46L, 58L, 62L, 64L, 65L, 66L, 67L, 68L, 69L, 73L, 85L, 98L, 2H, 4H, 36H, 39H, 43H, 45H, 69H, 70H, 74H, 75H, 76H, 78H, and 92H, utilizing the numbering system set forth in Kabat.

(Ex. 2004, Preliminary Amendment in the '117 application, filed 28 October 2004, p. 3).

12. Claims 31 and 32 of the '117 application depended on claim 30.  
(Ex. 2004, Preliminary Amendment in the '117 application, filed 28 October 2004, p. 4).

13. During ex parte prosecution, Adair did not indicate where the specification of the '117 application supports claims 30-32. (Ex. 2004, Preliminary Amendment to the '117 application, filed 28 October 2004).

14. Adair cancelled claims 30-32 of the '117 application in a Preliminary Amendment filed 4 November 2004. (Ex. 2005, Third Preliminary Amendment Deleting Claims 30-32, filed 4 November 2004, p. 3).

15. The Adair PCT application was filed 21 December 1990. (Ex. 2011; Adair PCT application), which is before the critical date.

16. Claim 6 of the Adair PCT application recites:

A CDR-grafted antibody light chain having a variable region domain comprising acceptor framework and donor antigen binding regions wherein the framework comprises donor residues at at least one of positions 1 and/or 3 and 46 and/or 47.

(Ex. 2011, Adair PCT application, p. 69<sup>2</sup>).

17. Claim 16 of the Adair PCT application recites:

A CDR-grafted antibody heavy or light chain or molecule according to any one of the preceding claims comprising human acceptor residues and non-human donor residues.

(Ex. 2011, Adair PCT application, p. 71).

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<sup>2</sup> Page numbers of exhibits refer to the numbering of the exhibit, not numbers printed on the underlying document.

18. The Adair PCT application was filed in the United States on 17 September 1991, as the Adair '329 application. (Ex. 2012, Adair '329 application transmittal, p. 87).

19. The Adair '329 application presented the same claims 6 and 16 of the Adair PCT application. (Ex. 2012, Adair '329 application, pp. 67 and 69).

20. An Office Action was mailed on 18 November 1992 in the Adair '329 application rejecting claim 6 under 35 U.S.C. § 112, second paragraph, for being indefinite because the Examiner found the phrase "at least one of positions 1 and/or 3 and 46 and/or 47" to be "unclear with regard to whether the light chain contains donor residues at at least one of (1 and/or 3) and (46 and/or 47) or alternatively (1) and/or (3 and 26[sic - 46]) and/or (47)." (Ex. 2053, Office Action of 18 November 1992 in the '329 application, p. 7).

21. In an Amendment following the Office Action of 18 November 1992, Adair cancelled claims 6 and 16. (Ex. 2013, Amendment filed 19 January 1993 in Adair '329 application, pp. 1-2).

### Analysis

35 U.S.C. § 135(b)(1) states that:

[a] claim which is the same as, or for the same or substantially the same subject matter as, a claim of an issued patent may not be made in any application unless such a claim is made prior to one year from the date on which the patent was granted.

A claim to the same or substantially the same subject matter as a claim of an issued patent is barred by §135(b)(1) unless timely presented. Thus,

135(b)(1) acts as a statute of repose placing a time limit on a patentee's exposure to an interference proceedings. *Regents of Univ. of Calif. v. Univ. of Iowa Res. Found.*, 455 F.3d 1371, 1376 (Fed. Cir. 2006). A claim to the same or substantially the same subject matter filed after one year from the date on which the patent was issued, the "critical date," is barred unless the "later filed claim does not differ from an earlier [pre-critical date] claim in any 'material limitation,'" *In re Berger*, 279 F.3d 975, 981-82 (Fed. Cir. 2002) (quoting *Corbett v. Chisholm*, 568 F.2d 759, 765-66 (CCPA 1977)). The Federal Circuit has explained that at least one reason for the restrictions on the nature of changes that may be made to post-critical date claims is to "prevent a patent applicant from relying on the filing date of a claim to which it was not statutorily entitled," when provoking an interference. *Regents of the Univ. of Cal. v. Univ. of Iowa Res. Found.*, 455 F.3d 1371, 1377 (Fed. Cir. 2006). Where an applicant changes a pre-critical date claim in response to an Examiner's rejection to obtain allowance of the claim, we presume that the change is a material one because it is necessary to patentability. See *Corbett*, 568 F.2d at 765 (where a party's claim lacked a method step, the court noted that the party did "not seriously contend that this [was] not a material limitation, that is necessary to patentability . . . ."); see also *Berger*, 279 F.3d at 982 (holding that a limitation added during prosecution to avoid the prior art is a "material limitation"), see also *Wetmore v. Miller*, 477 F.2d 960, 964 (1973) ("the 'fusible' limitation of appellant's claims must be regarded as not necessary to patentability and not 'material' for present purposes [of complying with 35 U.S.C. § 135(b)]").



The involved Adair claim was filed over one year after the Carter claims issued and thus on its face is barred by § 135(b)(1). However, Adair may avoid the bar if it had a claim filed prior to the critical date that does not differ materially from its involved claim.

When Adair requested an interference with the involved Carter '055 patent, it relied on claims 30-32 of the '117 application (FFs 7 and 9; Ex. 2004, Amendment to the '117 application, filed 28 October 2004, p. 3-4; Ex. 2006, Preliminary Amendment and Request for Interference in application no. 11/284,260, filed 21 November 2005, p. 4) to show that claim 26 is not barred by § 135(b)(1). Indeed, Adair copied claims 30-32 from involved claims 1-3 of the Carter '055 patent (FF 8; Ex. 2004, Preliminary Amendment to the '117 application, filed 28 October 2004, p. 5) before the critical date (FF 10).

However, in its Opposition, Adair appears to shift positions and asserts that claim 16, which depends from claim 6, (FFs 16 and 17; Ex. 2011, Adair PCT application, pp. 69 and 71) of the PCT application was filed before the critical date (FF 15; Ex. 2011; Adair PCT application) and provides sufficient support such that claim 26 is not barred by § 135(b). (Reply at 5-6).

We consider below whether any of these claims would allow Adair to avoid the bar of §135(b)(1) in view of the arguments and evidence before us.

*Claims 30-32 of the '117 Application*

Claim 30 of the '117 application recited:

A humanized antibody variable domain comprising non-human CDR amino acid residues which bind an antigen incorporated into a human antibody variable domain, and further

comprising a Framework Region (FR) amino acid substitution at a site selected from the group consisting of:

4L, 35L, 38L, 43L, 44L, 46L, 58L, 62L, 64L, 65L, 66L, 67L, 68L, 69L, 73L, 85L, 98L, 2H, 4H, 36H, 39H, 43H, 45H, 69H, 70H, 74H, 75H, 76H, 78H, and 92H, utilizing the numbering system set forth in Kabat.

(FF 10; Ex. 2004, Preliminary Amendment in the '117 application, filed 28 October 2004, p. 3). Claims 31 and 32 depended on claim 30. (FF 12; Ex. 2004, Preliminary Amendment in the '117 application, filed 28 October 2004, p. 4). Adair cancelled claims 30-32 before they were examined. (FF 14). Thus, there is no record from the Examiner regarding their patentability.

Claims 30-32 differ from the involved Adair claim in that they recite many more positions than the single position (46L) in the involved claim. (See FF 3, Paper 5). According to Carter, involved claim 26 is materially different than claims 30-32 of Adair's '117 application and was determined to be patentable by the Examiner only because of the change in the material limitations by deleting positions recited in the Markush group. (Motion 14). Carter further notes that when Adair filed claims 30-32 of the '117 application it did not point to support in the specification. (See Adair Response to MF 7, admitted by Adair). In its Opposition, Adair also fails to point to a description of substitution of residues 43L, 43H, 70H, 74H, and 92H in the '117 application specification. Nor does Adair provide sufficient evidence that those of skill in the art would have understood the '117 description to show substitution of these residues at these positions despite the lack of express recitation.

We do not speculate as to why Adair cancelled claims 30-32 and note that an applicant is entitled to rely upon cancelled claims for pre-critical date support. *Corbett v. Chisholm*, 568 F.2d 759, 765 (Fed. Cir. 1977). However, on their face claims 30-32 are of such different scope than claim 26 that claim 26 appears to be materially different. Carter's arguments that claims 30-32 were not patentable because they lack written description support in the specification and Adair's lack of persuasive argument or evidence to the contrary serve to reinforce that the change resulting in claim 26 was a material one.

We are persuaded that Adair changed material limitations in pre-critical date claims 30-32 to arrive at the involved claim 26. Thus, Adair cannot rely on claims 30-32 to avoid the bar of § 135(b)(1) for involved claim 26.

*Claims 6 and 16 of the PCT Application*

Claim 6 of Adair's PCT application recites:

A CDR-grafted antibody light chain having a variable region domain comprising acceptor framework and donor antigen binding regions wherein the framework comprises donor residues at at least one of positions 1 and/or 3 and 46 and/or 47.

(FF 16; Ex. 2011, Adair PCT application, p. 69), while claim 16 of the PCT application recites:

A CDR-grafted antibody heavy or light chain or molecule according to any one of the preceding claims comprising human acceptor residues and non-human donor residues.

(FF 17; Ex. 2011, Adair PCT application, p. 71). Adair asserts that claim 16, along with claim 6 on which it depends, provides pre-critical date support sufficient to avoid the bar of 35 U.S.C. § 135(b)(1). (Opposition at 5-6).

According to Adair, claim 6 requires that only one of the recited residues be substituted, providing support for Adair's later-filed involved claim drawn to substitution at position 46. (*Id.*).

Carter argues that PCT claims 6 and 16 do not provide a basis for Adair to avoid the bar because the involved Adair claim differs materially from claims 6 and 16. (Reply 5-9). Carter cites to the Examiner's rejection of claim 6 in the '329 application under 35 U.S.C. § 112, second paragraph, as being indefinite.<sup>3</sup> (FF 20, Ex. 2053, Office Action of 18 November 1992, in the '329 application, p. 7). In that rejection, the Examiner found that the phrase "at least one of positions 1 and/or 3 and 46 and/or 47" was "unclear with regard to whether the light chain contains donor residues at at least one of (1 and/or 3) and (46 and/or 47) or alternatively (1) and/or (3 and 26[sic - 46]) and/or (47)." (Ex. 2053, Office Action of 18 November 1992 in the '329 application, p. 7). Indeed, only after Adair cancelled claims 6 and 16 in the '329 application was later-filed involved claim 26, allowed, indicating that the changes to claims 6 and 16 were necessary to patentability. Carter argues that PCT claim 6 differs in a material limitation from Adair's involved claim 26, because the latter recites substitution only at position 46. (Reply 7-8).

The Examiner's allowance of the involved claim only after claims 6 and 16 were cancelled is evidence of materiality. See *Univ. of Calif.*, 455 F.3d at 1376 ("When a party seeks to add a new claim, or to amend an existing claim, beyond the critical date for section 135(b)(1), this court applies the material differences

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<sup>3</sup> We also note that PCT claims 6 and 16 were also rejected under 35 U.S.C. §§ 101, 102, 103, and 112, first paragraph. (Ex. 2053).

test discussed in opinions like *Berger* to determine if ‘such a claim’ is barred.”).

Adair argues only that “[r]egardless of where hypothetical parentheticals would go, it is clear that **one** or more of the recited residues are to be donor.”

(Opposition 4 (emphasis in original)) and that Carter has not presented evidence that one of skill in the art would have found the phrase to be indefinite.

However, under either reading of claim 16, the claim differs in scope from involved claim 26 because it covers positions in addition to 46, (Opposition 5).

Adair’s arguments that claim 26 does not differ materially rely only upon attorney argument. “Argument of counsel cannot take the place of evidence lacking in the record.” *Meitzner v. Mindick*, 549 F.2d 775, 782 (CCPA 1977).

We further note that Adair did not seek authorization to file a responsive motion to add PCT claims 6 and 16 to its involved application. Adair asserts that filing a responsive motion to add PCT claims 6 and 16 to this interference would be “futile” because of the requirement to certify that it is not aware of any reason why the claims are not patentable (citing SO ¶ 208.5.1). (Opposition 6-7). However, the Standing Order would not prevent Adair from presenting arguments and evidence to show that these claims were indeed patentable to Adair.

On the record before us, we are persuaded that differences between Adair’s PCT claims and Adair’s involved claim are material limitations. *Cf. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 734 (2002) (“A rejection indicates that the patent examiner does not believe the original claim can be patented. While the patentee has the right to appeal, his decision to forgo an appeal and submit an amended claim is taken as a concession that the

invention as patented does not reach as far as the original claim.”). Accordingly, we are not persuaded that Adair can rely on PCT claims 6 and 16 to avoid the bar of 35 U.S.C. § 135(b)(1).

### III. ORDER

Upon consideration of the motions, and for the reasons given, it is ORDERED that Carter Motion 1 for judgment that Adair claim 26 is barred under 35 U.S.C. § 135(b)(1) is GRANTED.

FURTHER ORDERED that judgment will be entered against Adair in a separate paper.

/ss/ Sally Gardner Lane  
SALLY GARDNER LANE  
*Administrative Patent Judge*

/ss/ Richard Torczon  
RICHARD TORCZON  
*Administrative Patent Judge*

/ss/ Sally C. Medley  
SALLY C. MEDLEY  
*Administrative Patent Judge*

cc (via electronic):

Attorney for Carter:  
Oliver R. Ashe, Jr., Esq.  
ASHE, P.C.  
11440 Isaac Newton Square North  
Suite 210  
Reston, VA 20190  
Email: oashe@ashepc.com

Jeffrey P. Kushan, Esq.  
SIDLEY AUSTIN LLP  
1501 K Street, N.W.  
Washington, D.C. 20005  
Email: jkushan@sidley.com

Attorney for Adair:  
Doreen Yatko Trujillo, Esq.  
Michael B. Fein, Esq.  
COZEN O'CONNOR P.C.  
1900 Market Street  
Philadelphia, PA 19103  
Email: dtrujillo@cozen.com  
Email: mfein@cozen.com